UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MICHAEL HANN, on behalf of himself and all others similarly situated, Plaintiff, v. Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Pvt. Ltd., Defendants.	Civil Action No. **CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Michael Hann ("Plaintiff") brings this action on behalf of himself and all others similarly situated against Defendants Amneal Pharmaceuticals of New York LLC and Amneal Pharmaceuticals Pvt. Ltd. (collectively "Defendants"). Defendants are subsidiaries of Amneal Pharmaceuticals, Inc.[1] Plaintiff makes the following allegations pursuant to the investigation of his counsel and based upon information and belief, except as to the allegations specifically pertaining to himself, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding Defendants' manufacturing,

[1] Plaintiff refers to Amneal Pharmaceuticals, Inc. and Defendants, collectively, as "Amneal."

distribution, and sale of the generic medication metformin that contains dangerously high levels of N-nitrosodimethylamine (NDMA), a carcinogenic and liver-damaging impurity.

2. Metformin is a prescription medication that has been sold under brand names such as Glucophage. Metformin is used to control high blood sugar in patients with type 2 diabetes. However, Amneal's manufacturing process has caused metformin to contain dangerously high levels of NDMA.

3. NDMA is a semi volatile organic chemical. According to the U.S. Environmental Protection Agency, NDMA "is a member of N-nitrosamines, a family of potent carcinogens."[2] While NDMA is not currently produced in the United States other than for research purposes, it was formerly used "in production of liquid rocket fuel," among other uses.[3] NDMA is listed as a "priority toxic pollutant" in federal regulations. *See* 40 CFR § 131.36. Exposure to NDMA can cause liver damage and cancer in humans. NDMA is classified as a probable human carcinogen,[4] and animal studies have shown that exposure to NDMA has caused

[2] EPA, Technical Fact Sheet – N-Nitrosodimethylamine (NDMA) (Jan. 2014), https://19january2017snapshot.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_ndma_january2014_final.pdf (last accessed Sept. 28, 2023).

[3] *Id.*

[4] *Id.*

tumors primarily of the liver, respiratory tract, kidney and blood vessels.[5]

4. On March 2, 2020, Valisure, an online pharmacy registered with the U.S. Drug Enforcement Agency and Food & Drug Administration, "detected high levels of NNitrosodimethylamine (NDMA) in specific batches of prescription drug products containing metformin."[6] This included metformin manufactured by Amneal.[7]

5. At the time Valisure submitted its petition, Amneal had not yet issued a recall of metformin and continued to tout its commitment to producing quality medicines on its website.[8] However, these representations are false, as Defendant's metformin medication contained the carcinogenic impurity NDMA.

A. Defendants Manufactured, Sold, and Distributed Defective Metformin-Containing Drugs

6. From at least 2018 to 2020, Amneal Pharmaceuticals Pvt. Ltd.

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[5] EPA, *N-Nitrosodimethylamine*, https://www.epa.gov/sites/default/files/2016-09/documents/n-nitrosodimethylamine.pdf (last accessed Sept. 28, 2023).

[6] VALISURE, VALISURE CITIZEN PETITION ON METFORMIN 1 (2020), https://www.valisure.com/wp-content/uploads/Valisure-FDA-Citizen-Petition-on-Metformin-v3.9.pdf (last accessed Apr. 7, 2020) (hereinafter "VALISURE PETITION").

[7] *Id.* at 9.

[8] Amneal, *Our Purpose & Commitments*, https://amneal.com/about/our-purpose-commitments/ (last accessed Sept. 28, 2023; *see also* May 18, 2019 Archived Webpage: Amneal, *Our Story*, https://web.archive.org/web/20190518163517/https://www.amneal.com/about/our-story/ (last accessed Sept. 28, 2023).

manufactured finished dose Metformin Hydrochloride Extended-Release Tablets that also contained N-nitrosodimethylamine (Amneal's metformin that also contained N-nitrosodimethylamine are referred to as "MCDs") at its Matoda, Gujarat, India manufacturing facility. Specifically, Amneal Pharmaceuticals Pvt. Ltd. manufactured 500 mg and 750 mg MCDs at its Matoda, Gujarat, India manufacturing facility. The MCDs manufactured by Amneal Pharmaceuticals Pvt, Ltd. were manufactured for the United States market and were sold and distributed in the United States, including in the States of New Jersey and California, under the Amneal brand. MCDs manufactured by Amneal Pharmaceuticals Pvt. Ltd. were distributed by Amneal Pharmaceuticals LLC, an Amneal subsidiary located in Bridgewater, New Jersey.

7. In or around 2008, Amneal acquired its ANDA to manufacture extended-release metformin from Interpharm. From 2008 to 2020, Amneal Pharmaceuticals of New York, LLC manufactured finished dose MCDs at its Hauppauge, New York manufacturing facility. Specifically, Amneal Pharmaceuticals of New York, LLC manufactured 500 mg and 750 mg MCDs at its Hauppauge, New York manufacturing facility. MCDs manufactured by Amneal Pharmaceuticals of New York, LLC were manufactured for the United States market and were sold and distributed in the United States, including in the States of New Jersey and California, under the Amneal brand.

8. Because Defendants manufactured their MCDs for the United States market, they had quality assurance obligations with respect to Amneal's processes and finished dose products pursuant to federal law.

9. As subsidiaries of Amneal Pharmaceuticals, Inc., Defendants were subject to the direction, oversight, management, and control of Amneal Pharmaceuticals, Inc. with respect to the manufacture, sale, testing, quality assurance, distribution, and sale of their MCDs in the United States.

10. As subsidiaries of Amneal Pharmaceuticals, Inc., Defendants were subject to the direction, oversight, management, and control of Amneal Pharmaceuticals, Inc., and specifically its global regulatory department responsible for assuring regulatory compliance and coordinating with regulatory agencies (including the U.S.F.D.A.) about the same. Upon information and belief, Defendants were subject to the direct control of Amneal Pharmaceuticals Inc. with respect to all aspects of regulatory compliance and regulatory communications functions for their Hauppauge, New York and Matoda, Gujarat, India manufacturing facilities which manufactured MCDs labeled as Amneal for distribution and/or sale in United States markets.

11. For over a decade prior to detection of NDMA in Amneal's MCDs, Amneal—including subsidiaries Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Pvt. Ltd.—was subjected to numerous inspections by the

FDA revealing quality assurance problems at Amneal facilities.

12. For example, in November 2009, the FDA inspected Amneal Pharmaceuticals of New York, LLC's facility in Hauppauge, New York, and identified quality assurance problems at that facility. This same facility is the facility identified by Amneal as one of its finished dose manufacturers for its MCDs.

13. More recently, in April 2018, the FDA inspected Amneal Pharmaceuticals Pvt. Ltd.'s facility in Matoda, Gujarat India, which was used to manufacture finished dose MCDs. The FDA cited Amneal Pharmaceuticals Pvt. Ltd. for not reviewing (or even requesting to review) raw data from testing it outsourced to third-party vendors.

14. On May 29, 2020, Amneal announced a recall of all lots of Metformin Hydrochloride Extended Release Tablets within expiry to the consumer level, through Amneal Pharmaceuticals, LLC.[9] The recall included Metformin Hydrochloride-Extended Release Tablets manufactured by both Amneal Pharmaceuticals Pvt. Ltd. at its Matoda, Gujarat, India, manufacturing facility and by Amneal Pharmaceuticals, LLC of New York at its Hauppauge, New York

[9] FDA, *Amneal Pharmaceuticals LLC Issues Voluntary Nationwide Recall of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, Due to Detection of N-Nitrosodimethylamine (NDMA) Impurity*, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended (last accessed Sept. 28, 2023).

manufacturing facility.

15. Importantly, the recall was limited to products within the expiry date only because it would have been impractical to recall products that were already expired. However, the contamination of the products began long before. Many contaminated pills were never recalled simply because they were expired already.

16. The recall included the following NDC codes manufactured by Amneal Pharmaceuticals Pvt. Ltd. at its Matoda, Gujarat, India manufacturing facility:

- 65162-179-10
- 65162-178-09
- 65162-178-50
- 65162-179-10
- 65162-178-11

17. The recall included the following NDC codes manufactured by Amneal Pharmaceuticals, LLC of New York at its Hauppauge, New York manufacturing facility:

- 53746-178-01
- 53746-178-05
- 53746-178-10
- 53746-178-90
- 53746-178-Bulk
- 53746-179-01
- 53746-179-Bulk

A. Amneal's Metformin Is Marketed as Safe

18. Amneal has always marketed metformin as a safe and effective product and has continued to do so despite the findings of Valisure.

19. Metformin is one of the most successful drugs in history. Metformin was the fourth most prescribed medication in the United States in 2017, with over 78.6 million prescriptions.[10]

20. On Amneal's website for its generic medications, Amneal touts that it "deliver[s] quality, trust, and value."

21. Amneal also notes on its website that "for close to 20 years [consumers] have associated the Amneal name with an unwavering commitment to quality, service, and value."

B. Amneal's Metformin Contains Dangerous Levels Of NDMA

22. Contrary to the above assertions, the MCDs contain dangerously high levels of NDMA that would not be present if they were properly manufactured. As noted in paragraph 4, *supra*, Valisure found unacceptable levels of NDMA in samples of metformin, including samples from Amneal.

23. While the cause of the NDMA contamination in metformin is still being investigated, Valisure notes that "the presence of NDMA in metformin products may be primarily due to contamination during manufacturing as opposed to a fundamental instability of the drug molecule."[11]

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[10] *The Top 300 of 2020*, CLINCALC, https://clincalc.com/DrugStats/Top300Drugs.aspx (last accessed Apr. 7, 2020).

[11] VALISURE PETITION 3.

24. The FDA has "set strict daily acceptable intake limits on NDMA in pharmaceuticals of 96 nanograms."[12] But Valisure found that Amneal's metformin has an NDMA content that is between 9 and nearly 17 times the daily intake limit.[13]

Company	Dose (mg)	Type	Lot	NDMA (ng/tablet)	Common Tablets/Day	Times Over Acceptable Daily Intake Limit of NDMA
Amneal Pharmaceuticals LLC	750	Metformin ER	AM180770A	450 +/- 100	4	9.4X
Amneal Pharmaceuticals LLC	500	Metformin ER	AM190107AA	395 +/- 53 (623 +/- 28)*[14]	4	16.5X

25. The presence of NDMA in metformin is particularly troubling because the medication is taken daily.[15]

26. Pursuant to its findings, Valisure recommended a recall of Amneal's metformin medications.[16]

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[12] *Id*. at 1.

[13] *Id*. at 9.

[14] The asterisk (*) denotes data generated by Emery Pharma from the same batch. VALISURE PETITION 8.

[15] *Id.* at 1https://www.cbsnews.com/news/zantac-ndma-levels-potentially-dangerous-chemical-zantac-ranitidine-heartburn-pills-2019-10-08/.

[16] *Id.* at 11-12.

27. On May 29, 2020, Amneal Pharmaceuticals LLC, announced that it was recalling all lots of Metformin Hydrochloride Extended-Release Tablets, 500 mg and 750 mg within expiry due to the detection of n-nitrosodimethylamine.[17] The recalled metformin products were manufactured, sold, and/or distributed by Defendants Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Pvt. Ltd.

C. Plaintiff Was Harmed By Purchasing And Consuming Defective Metformin Manufactured By Defendant

28. Plaintiff and the Class were injured by the full purchase price of their metformin medications. These medications are worthless, as they contain harmful levels of NDMA. As the medications expose users to NDMA well above the legal limit, the medications are not fit for human consumption. Plaintiff is further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely toxic NDMA, and for damages related to Defendant's conduct.

29. Plaintiff brings this action on behalf of himself and the Class for equitable relief and to recover damages and restitution for: (i) breach of the implied warranty of merchantability, (ii) unjust enrichment, (iii) fraudulent concealment,

[17] FDA, Amneal Pharmaceuticals LLC Issues Voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg, Due to Detection of N-Nitrosodimethylamine (NDMA) Impurity, (June 1, 2020), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended (last accessed Sept. 18, 2023).

(iv) fraud, (v) conversion, and (vi) violation of California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq*.

PARTIES

30. Plaintiff Michael Hann is a citizen of California who resides in San Francisco, California. Mr. Hann has been taking metformin since 2018. During all relevant time periods, Mr. Hann was prescribed, purchased and consumed metformin manufactured, sold, and/or distributed by Defendants, for which he paid a co-pay of approximately $3.40. Mr. Hann originally learned about the metformin defect on the news. Further investigation revealed that Mr. Hann has been using the defective metformin manufactured by Amneal for some time. When purchasing metformin from Defendants, Mr. Hann reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly manufactured, free from defects, and safe for their intended use. Mr. Hann relied on these representations and warranties in deciding to purchase metformin from Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased metformin from Defendants if he had known it was not, in fact, properly manufactured and free from defects. Mr. Hann also understood that each purchase involved a direct transaction between himself and Amneal because his medication came with packaging and other materials

prepared by Amneal, including representations and warranties that his medications were properly manufactured and free from defects.

31. Amneal Pharmaceuticals Pvt. Ltd. is an Indian company with its principal place of business at Plot No. 16 and 17, PHARMEZ Special Economic Zone, Sarkhej Bhavla NJ No. 8A, vil. Matoda, Tal. Sanandm District: Ahmedabad – 382213, Gujarat, India. Amneal Pharmaceuticals Pvt. Ltd. conducts substantial business in the United States and has been engaged in the manufacturing, distribution, and sale of defective metformin in the United States, including specifically in the States of New Jersey and California.

32. Amneal Pharmaceuticals of New York, LLC is a New York limited liability company with its principal place of business at 75 Adams Avenue, Hauppauge, New York, USA 11788. Amneal Pharmaceuticals of New York conducts substantial business in the United States and has been engaged in the manufacturing, distribution, and sale of defective metformin in the United States, including specifically in the States of New Jersey and California.

JURISDICTION AND VENUE

33. This Court has personal jurisdiction over Defendants because Defendants have sufficient minimum contacts in New Jersey and because Defendants have otherwise intentionally availed themselves of markets within New Jersey through their business activities, such that the exercise of jurisdiction by this

Court is proper and necessary. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendant, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

34. Venue is proper in this District under 28 U.S.C. § 1391(a) because of the consolidation in this district, because a substantial part of the events or omissions giving rise to the claim occurred in this district, and because Defendants are subject to the personal jurisdiction of this Court. 28 U.S.C. § 1391(b)(3).

CLASS ALLEGATIONS

35. Plaintiff seeks to represent a class defined as all persons in the United States who purchased metformin manufactured by Amneal (the "Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or Defendants' officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

36. Plaintiff also seeks to represent a subclass of all Class members who purchased metformin in California (the "Subclass").

37. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class and Subclass may be expanded or narrowed by amendment or amended complaint.

38. **Numerosity.** The members of the Class and Subclass are geographically dispersed throughout the United States and the State of California and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class and Subclass. Although the precise number of Class members is unknown to Plaintiff, the true number of Class and Subclass members is known by Defendants and may be determined through discovery. Class and Subclass members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendants and third-party retailers and vendors.

39. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and Subclass and predominate over any questions affecting only individual Class and Subclass members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the metformin manufactured by Defendants contains

dangerously high levels of NDMA, thereby breaching the implied warranties made by Defendants and making metformin unfit for human consumption and therefore unfit for its intended purpose;

(b) whether Defendants knew or should have known that metformin contained elevated levels of NDMA prior to selling the medication, thereby constituting fraud and/or fraudulent concealment;

(c) whether Defendants have unlawfully converted money from Plaintiff and the Class and Subclass;

(d) whether Defendants are liable to Plaintiff and the Class and Subclass for unjust enrichment;

(e) whether Defendants are liable to Plaintiff and the Class and Subclass for fraudulent concealment;

(f) whether Plaintiff and the Class and Subclass have sustained monetary loss and the proper measure of that loss;

(g) whether Plaintiff and the Class and Subclass are entitled to declaratory and injunctive relief;

(h) whether Plaintiff and the Class and Subclass are entitled to restitution and disgorgement from Defendants; and

(i) whether the marketing, advertising, packaging, labeling, and other promotional materials for metformin are deceptive.

40. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class and Subclass in that Defendants mass marketed and sold defective metformin to consumers throughout the United States. This defect was present in all of the metformin manufactured by Defendants. Therefore, Defendants breached its implied warranties to Plaintiff and Class and Subclass members by manufacturing, distributing, and selling the defective metformin. Plaintiff's claims are typical in that he was uniformly harmed in purchasing and consuming the defective metformin. Plaintiff's claims are further typical in that Defendants deceived Plaintiff in the very same manner as they deceived each member of the Class and Subclass. Further, there are no defenses available to Defendants that are unique to Plaintiff.

41. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class and Subclass. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Class and Subclass. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class and Subclass.

42. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or

other financial detriment suffered by individual Class and Subclass members are relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for the Class and Subclass, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class and Subclass members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

43. In the alternative, the Class and Subclass may also be certified because:

(a) the prosecution of separate actions by individual Class and Subclass members would create a risk of inconsistent or varying adjudications with respect to individual Class and Subclass members that would establish incompatible standards of conduct for the Defendants;

(b) the prosecution of separate actions by individual Class and

Subclass members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class and Subclass members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendants have acted or refused to act on grounds generally applicable to the Class and Subclass as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class and Subclass as a whole.

COUNT I
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of The Class And Subclass)

44. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

45. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the Subclass against Defendants.

46. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that metformin (i) would not contain elevated levels of NDMA and (ii) is generally recognized as safe for human consumption.

47. Defendants breached the warranty implied in the contract for the sale of the defective metformin because it could not pass without objection in the trade

under the contract description, the metformin was not of fair or average quality within the description, and the metformin was unfit for its intended and ordinary purpose because the metformin manufactured by Defendants was defective in that it contained elevated levels of carcinogenic and liver toxic NDMA, and as such is not generally recognized as safe for human consumption. As a result, Plaintiff and Class and Subclass members did not receive the goods as impliedly warranted by Defendant to be merchantable.

48. Plaintiff and Class and Subclass members purchased metformin in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

49. The metformin was not altered by Plaintiff or Class and Subclass members.

50. The metformin was defective when it left the exclusive control of Defendants.

51. Defendants knew that the metformin would be purchased and used without additional testing by Plaintiff and Class and Subclass members.

52. The defective metformin was defectively manufactured and unfit for its intended purpose, and Plaintiff and Class and Subclass members did not receive the goods as warranted.

53. As a direct and proximate cause of Defendants' breach of the implied

warranty, Plaintiff and Class and Subclass members have been injured and harmed because: (a) they would not have purchased metformin on the same terms if they knew that metformin contained harmful levels of NDMA, and is not generally recognized as safe for human consumption; and (b) metformin does not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

COUNT II
Unjust Enrichment
(On Behalf Of The Class And Subclass)

54. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

55. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Subclass against Defendants.

56. Plaintiff and the Class and Subclass conferred a benefit on Defendant in the form of monies paid to purchase Defendants' defective metformin.

57. Defendants voluntarily accepted and retained this benefit.

58. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for medications unfit for human use, it would be unjust and inequitable for the Defendants to retain it without paying the value thereof.

COUNT III
Fraudulent Concealment
(On Behalf Of The Class and Subclass)

59. Plaintiff hereby incorporates by reference the allegations contained in

all preceding paragraphs of this complaint.

60. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Subclass against Defendants.

61. Defendants had a duty to disclose material facts to Plaintiff and the Class and Subclass given their relationship as contracting parties and intended users of metformin. Defendants also had a duty to disclose material facts to Plaintiff and the Class and Subclass, namely that they were in fact manufacturing, distributing, and selling harmful metformin unfit for human consumption, because Defendants had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

62. Defendants possessed knowledge of these material facts. Since at least December 2019, Defendants have been aware that NDMA was detected in metformin-containing medications in other nations.[18] During this time, Plaintiff and Class and Subclass members were using their medications without knowing they contained dangerous levels of NDMA.

63. Defendants failed to discharge their duty to disclose these materials facts.

64. In so failing to disclose these material facts to Plaintiff and the Class

[18] *FDA Investigates NDMA in Metformin*, U.S. PHARMACIST (Dec. 20, 2019), https://www.uspharmacist.com/article/fda-investigates-ndma-in-metformin (last accessed Mar. 9, 2020).

and Subclass, Defendants intended to hide from Plaintiff and the Class and Subclass that they were purchasing and consuming metformin with harmful defects that was unfit for human use, and thus acted with scienter and/or an intent to defraud.

65. Plaintiff and the Class and Subclass reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the defective metformin manufactured sold by Defendants had they known it contained unsafe levels of NDMA.

66. As a direct and proximate cause of Defendants' fraudulent concealment, Plaintiff and the Class and Subclass suffered damages in the amount of monies paid for the defective metformin.

67. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT IV
Fraud
(On Behalf Of The Class and Subclass)

68. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

69. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Subclass against Defendants.

70. As discussed above, Defendants provided Plaintiff and Class and Subclass members with materially false or misleading information about the

metformin manufactured by Defendants. Specifically, Defendants marketed metformin as safe for human consumption. As indicated above, however, these representations are false and misleading as Defendants' metformin medications contained elevated levels of NDMA.

71. The misrepresentations and omissions of material fact made by Defendant, upon which Plaintiff and Class and Subclass members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class and Subclass members to purchase defective metformin.

72. Defendants knew or should have known that their metformin was contaminated with this harmful impurity, but continued to manufacture it nonetheless. Since at least December 2019, Defendants have been aware that NDMA was detected in metformin medicines in other nations.[19] During this time, Plaintiff and Class and Subclass members were using the medication without knowing it contained dangerous levels of NDMA.

73. The fraudulent actions of Defendants caused damage to Plaintiff and Class and Subclass members, who are entitled to damages and other legal and equitable relief as a result.

74. As a result of Defendants' willful and malicious conduct, punitive

[19] *FDA Investigates NDMA in Metformin*, U.S. PHARMACIST (Dec. 20, 2019), https://www.uspharmacist.com/article/fda-investigates-ndma-in-metformin (last accessed Mar. 9, 2020).

damages are warranted.

COUNT V
Conversion
(On Behalf Of The Class And Subclass)

75. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

76. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Subclass against Defendants.

77. Plaintiff and the Class and Subclass have an ownership right to the monies paid for the defective metformin manufactured by Defendants.

78. Defendants have wrongly asserted dominion over the payments illegally diverted to them for the defective metformin. Defendants have done so every time that Plaintiff and the Class and Subclass bought metformin over the counter.

79. As a direct and proximate cause of Defendants' conversion, Plaintiff and the Class and Subclass suffered damages in the amount of the payments made for each time they bought metformin over the counter.

COUNT VI
Violation Of California's Unfair Competition Law, California Business & Professions Code §§ 17200, *et seq.*

80. Plaintiff incorporates by reference and re-alleges herein all paragraphs alleged above.

81. Plaintiff brings this claim individually and on behalf of the members of the proposed Subclass against Defendants.

82. By committing the acts and practices alleged herein, Defendants violated California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.* as to the Class, by engaging in unlawful, fraudulent, and unfair conduct.

83. Defendants violated the UCL's proscription against engaging in unlawful conduct because of its violations of the CLRA, Cal. Civil Code §§ 1770(a)(5), (a)(7), (a)(9), and (a)(16).

84. Defendants' acts and practices described above violate the UCL's proscription against engaging in fraudulent conduct.

85. As more fully described above, Defendants marketed metformin as safe for human consumption. As indicated above, however, these representations are false and misleading as Defendants' metformin medications contained elevated levels of NDMA. These representations were likely to deceive reasonable consumers.

86. Defendants' acts and practices described above also violate the UCL's proscription against engaging in unfair conduct.

87. Plaintiff and the other Subclass members suffered a substantial injury by virtue of buying metformin that they would not have purchased absent

Defendants' unlawful, fraudulent, and unfair marketing, advertising, packaging, and omission about the contaminated nature of its metformin medication, or by virtue of paying an excessive premium price for the unlawfully, fraudulently, and unfairly marketed, advertised, packaged, and labeled metformin medication.

88. There is no benefit to consumers or competition from deceptively marketing and omitting material facts about the contaminated nature of the metformin medication.

89. Plaintiff and the other Subclass members had no way of reasonably knowing that the metformin medication they purchased was not as marketed, advertised, packaged, or labeled. Plaintiff and the other Subclass members are not able to test for the presence of NDMA in their metformin medications. Thus, Plaintiff and the other Subclass members could not have reasonably avoided the injury each of them suffered.

90. The gravity of the consequences of Defendants' conduct, as described above, outweighs any justification, motive, or reason therefore, particularly considering the available legal alternatives which exist in the marketplace, and such conduct is immoral, unethical, unscrupulous, offends established public policy, or is substantially injurious to Plaintiff and the other members of the Subclass.

91. Defendant's violation has continuing and adverse effects because Defendant's unlawful conduct is continuing, with no indication that Defendant

intends to cease this fraudulent course of conduct. The public and class members are subject to ongoing harm because Defendant has not issued a recall for its contaminated metformin medication.

92. Plaintiff and the Subclass lost money or property as a result of Defendants' UCL violations because: (a) they would not have purchased metformin on the same terms if they knew that metformin contained harmful levels of NDMA and is not generally recognized as safe for human consumption; and (b) metformin does not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

93. Pursuant to California Business and Professional Code § 17203, Plaintiff and the Subclass seek an order of this Court that includes, but is not limited to, an order requiring Defendants to: (a) provide restitution to Plaintiff and the other Subclass members; (b) disgorge all revenues obtained as a result of violations of the UCL; and (c) pay Plaintiff's and the Subclass' attorney's fees and costs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendants, as follows:

(a) For an order certifying the nationwide Class and the Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as the representative for the Class and Subclass and Plaintiff's attorneys as Class Counsel;

(b) For an order declaring the Defendants' conduct violates the statutes referenced herein;

(c) For an order finding in favor of Plaintiff, the nationwide Class, and the Subclass on all counts asserted herein;

(d) For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

(e) For prejudgment interest on all amounts awarded;

(f) For an order of restitution and all other forms of equitable monetary relief;

(g) For injunctive relief as pleaded or as the Court may deem proper; and

(h) For an order awarding Plaintiff and the Class and Subclass their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable of right.

Dated: December 5, 2023 Respectfully submitted,

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